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Anxiety among women with mild dyskaryosis: a randomized trial of an educational intervention

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SUMMARY

Background. *Women with mild dyskaryosis are currently managed by six-month cytological surveillance. While there is good evidence that women suffer psychological distress on receipt of an abnormal test, and that this is amenable to educational intervention, it remains uncertain whether this distress is prolonged and, if so, how it should best be managed.*

Aim. *To investigate whether a structured educational intervention containing a risk communication package impacts upon psychological sequelae associated with this surveillance.*

Method. *A pragmatic cluster-randomized controlled trial during 14 months in 1995 and 1996, based in general practices in Avon and South Glamorgan, that compared the intervention with standard care. Follow-up was by postal questionnaire at six weeks and four months after the screening laboratory had reported the test result. The intervention was an invitation to attend the general practice to consult with a practice nurse trained to deliver the package. The main outcome measures were Spielberger state-anxiety, SF-36 Mental Health dimension, four condition-specific questions regarding concerns about gynaecological health and timing of the repeat smear test, and attendance for the repeat test.*

Results. *Of 514 eligible women, 270 were recruited, of whom 240 returned the six-week questionnaire and 181 returned the four-month questionnaire. On all but one outcome measure, the differences between the groups were not statistically significant. At six-week follow-up, the proportion who preferred the repeat test to be sooner than six months was statistically significantly higher among controls (74% versus 53%; 95% CI = 9% to 33%). At the four-month follow-up, the difference was 7% (95% CI = -7% to 21%).*

Conclusion. *There appear to be high levels of anxiety during surveillance for mild dyskaryosis that were not reduced by the intervention. Given that a personally delivered educational intervention designed to reduce anxiety could be viewed as the best available practice, it is of concern that women in the intervention group demonstrated sustained anxiety over a four-month period. The research agenda therefore seems to return to the fundamental question of whether surveillance should be the management of choice.*

Keywords: mild dyskaryosis; surveillance; anxiety; educational intervention; risk communication.

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Introduction

RATHER than offering immediate colposcopy, the National Health Service (NHS) Cervical Screening Programme policy since 1992 has been to place women with mildly dyskaryotic smear results under surveillance for six months before carrying out a repeat smear test.[1,2] If dyskaryosis persists, women are then offered colposcopy. Since mild dyskaryosis occurs at a rate of about 1–3 per 100 smear tests,[3,4] a substantial number of women are placed under surveillance. However, a randomized controlled trial of immediate colposcopy versus surveillance for mild/moderate dyskaryosis conducted in Aberdeen questioned the policy of surveillance.[3] The optimal management of women with mildly dyskaryotic smear results therefore remains uncertain in terms of disease outcome, cost, and acceptability.

There is considerable evidence that receipt of a dyskaryotic smear result is distressing,[5-7] and it has been suggested that this can be ameliorated by appropriate counselling and simple educational material in the form of a leaflet.[8] In particular, there is evidence that the latter is effective in terms of reducing state-anxiety immediately after receiving an abnormal smear result.[8]

The aim of the present study was to evaluate a structured educational intervention comprising a risk communication package delivered by practice nurses in a primary care setting. The main objective was to investigate its impact on the sustained psychological sequelae associated with surveillance for mild dyskaryosis.[9]

A pragmatic randomized controlled trial was designed to compare levels of anxiety, costs, and adherence to the six-month repeat smear test between a group of women receiving such an intervention in addition to 'standard care' and a control group receiving 'standard care' only — the latter included receipt of the previously evaluated leaflet.[8] The intervention comprised an invitation to attend the primary care centre for a consultation with a practice nurse who had been trained to deliver the educational package. The aim of this paper is to present the results of the effectiveness of this intervention; the cost implications are reported elsewhere.[10]

Method

Recruitment and allocation

The trial was conducted in two health authority areas and with the approval of the four ethics committees. Between November 1994 and January 1995, all 73 general practices in South Glamorgan and 129 in Avon were invited to participate. Women were eligible for inclusion if they had a first-time mildly dyskaryotic cervical smear result following a test carried out in a participating general practice. The research team were notified of women eligible for the trial by the cytology laboratories on a weekly basis over 14 months. After confirming that each woman had received her result, the research team contacted by telephone those considered by their GP as suitable for inclusion in the trial.

Those who agreed were sent an information sheet and consent form. Women in the intervention group were then contacted by their practice nurses to make an appointment to visit the practice; the control group received the conventional care offered by the practice they attended. Both groups were sent an additional information leaflet about cervical screening.[8]

Since it was impractical to ask practice nurses to carry out the intervention for some women and not others, the practice was chosen as the unit of randomization. Allocation to intervention or control was stratified by area and number of partners. The latter was performed primarily in order to ensure balance between the randomization groups in terms of practice size, with the corollary that the number of women in each group would be more likely to be similar. Allocation of practices was performed using computer-generated random numbers by an individual not involved in practice recruitment.

Sample size

The target was 120 women in each group across the two areas. This gave 80% power to detect, as significant at the two-sided 5% level, differences between the groups of 0.36 standard deviations.[11] For example, this translates to about 6.5 points for the mean of almost every subscale of the SF-36; roughly double this difference has been observed between groups of individuals who have and who have not consulted a doctor during the past two weeks.[12] For binary outcomes, this sample size yielded 80% power to detect differences of around 15%.

The impact on power of randomization by practice rather than by individual was unknown but was expected to be minimal since the numbers of recruits anticipated per practice were very small (on average approximately two). The sample size was therefore not subjected to any inflation factor, although clustering effects were adjusted for in the analyses.[13,14]

The intervention

All women received a previously evaluated leaflet containing information about cervical screening, including the message that an abnormal smear 'does not mean you have cancer'.[8] The intervention was an invitation to consult a practice nurse trained to present information from a specifically designed educational package, ideally within four weeks of receiving the smear result. The package comprised an A4 folder with 12 pages of information for the practice nurse to use and a condensed A5 version for the woman to take home. The package first aimed to clarify the distinction between pre-cancer and cancer. Secondly, information was given in pictorial form concerning the risk of developing cervical dyskaryosis compared with the much lower risk of developing cervical cancer. The final component covered future management. Throughout the intervention the woman was encouraged to raise questions regarding her central concerns.

Outcome measures

Women were sent an initial questionnaire after approximately six weeks, and a second questionnaire four months later, following the date that their result had been reported by their screening laboratory. The first questionnaire comprised condition-specific questions addressing the following issues: perceptions of gynaecological health, sexual life, and cervical smear testing. It also included the SF-36 generic instrument of health status,[12,15] measures of anxiety and stress over life events,[16-18] some questions on costs, and basic demographic characteristics. In addition, women were asked for free-text comments, both in general and with particular regard to their understanding of their test result. Women who had not returned their initial questionnaire within two weeks were sent a reminder; non-responders to this were not followed-up further. The four-month questionnaire was a shortened version of the first.

Five primary outcome variables were selected *a priori* from the initial questionnaire: current self-reported gynaecological health, level of concern about waiting for the repeat smear test, preferred interval before this test, Spielberger state-anxiety score, and the SF-36 Mental Health dimension. The first three of these are Likert-type scales, the latter two are validated quantitative scores.[12,15-17] For state-anxiety, the shortened six-item version was used, with scores scaled up to the range 20–80 to be consistent with the full scale.[16,17] In addition, attendance for the repeat smear (ascertained directly from the screening laboratories) was the sixth primary outcome variable. The remaining five condition-specific questions, the Impact of Events Scale (two subscales and the total scale[18]), and the other seven dimensions of the SF-36 were the 15 secondary outcomes.

Statistical analysis

For process measures, simple descriptive statistics such as proportions and means were used. The primary analysis for each of the outcomes compared the two randomization groups on an intention-to-treat basis. For categorical and quantitative outcomes, this involved chi-squared or *t*-tests and associated 95% confidence intervals for differences between proportions or means respectively. A 5% significance level was used for all primary outcomes. Applying the Bonferroni correction to the secondary outcomes meant that only *P*-values below 0.0033 were considered significant.[11]

The secondary analyses included a planned sub-group analysis comparing randomization groups according to whether or not the patient visited the practice. The methods employed were simple stratified analyses and interactions in generalized linear models to investigate whether the intervention effect was more (or less) marked among women who visited the practice.[11] Adjustments were also made for the confounding effects of the length of time between receipt of the smear test result and when the initial questionnaire was returned. Finally, clustering effects attributable to randomization by practice were taken into account for the primary outcomes.[13,14]

Results

Recruitment, progress, and comparability of the randomization groups

In South Glamorgan and in Avon, 58 (75%) and 67 (52%) practices took part respectively. Over 14 months of recruitment, a total of 573 women were registered with these practices when they received a mildly dyskaryotic smear result. In 59 cases the research team was not given permission to approach the patient. Reasons given included the patient having a history of serious illness, inability to speak English, concerns about the patient's mental health, and unsuitability for the trial. All the remaining 514 women were invited to participate in the trial. Of these, 270 (53%) consented and 240 (47%) women from 96 practices returned the initial questionnaire (Figure 1); of the 30 who did not, 15 were in each randomization group. As indicated in Figure 1, non-participation among the 514 women invited was primarily owing to difficulties with making telephone contact and obtaining consent from women in time to be included in the trial. This three-week time frame was the same for both groups and was chosen so that appointments could be arranged in the intervention group to take place prior to the women in both groups receiving the initial outcome questionnaire. Relatively few (n = 43) women who were contacted actively refused to participate.

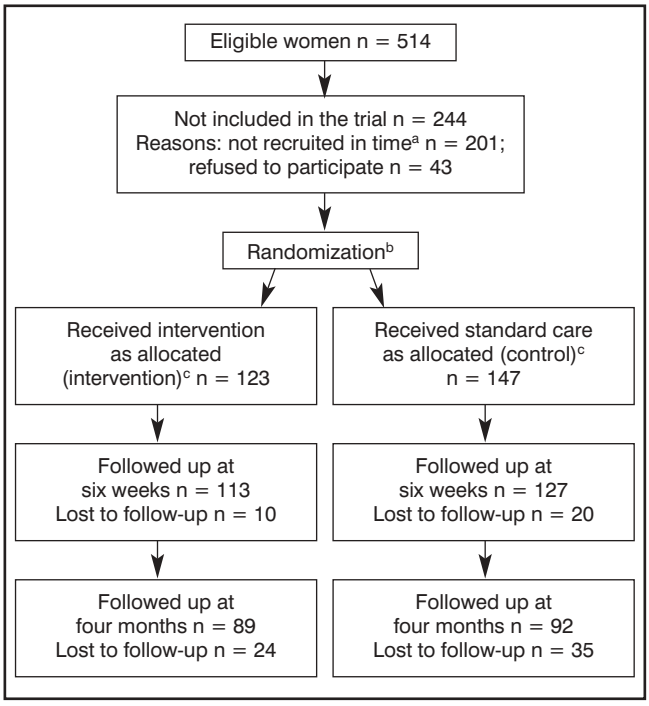

Figure 1. Flow chart describing progress of women through the trial. [a]Recruitment procedure: checking with the practice that the patient was sent her result and was suitable for the trial, introductory letter sent to the patient, telephone call to ensure result received (where telephone number available), detailed information sheet sent and written consent obtained (all within approximately 21 days of the laboratory notifying the research team). [b]Practices were randomized: 47 to intervention, 49 to control. [c]In a pragmatic design, with the intervention defined as an invitation to attend for counselling, all women in both groups received their allocated model of care. Details of visits to the practice are given in Table 3.

The age distribution of the women and practice characteristics (number of partners and randomization group) were almost identical between the participants and the non-participants. In addition, the initial response rate of 89% (240/270) of those consenting was practically the same for the two areas. The overall response rate for the four-month questionnaire was 67% (181/270).

The two randomization groups were very similar in terms of age and employment status (Table 1). Although the proportion with the highest educational qualifications was slightly greater for controls, the difference is unlikely to have an impact on the outcome measures. Moreover, the proportions with no qualifications were effectively the same.

Outcomes: primary analyses

Of the five primary outcomes from the questionnaire, one was statistically significant at the 5% level (Table 2). Controls were more likely to prefer the repeat smear test to be sooner than in six months time. In addition, although the overall chi-squared test was marginally non-significant, there was evidence to suggest that the proportion of women expressing some degree of concern about waiting six months was higher in the control group (Table 2); the proportion 'very concerned' was about 14% in both groups. For the two standard anxiety measures, there was no evidence of differences between the randomization groups — in both cases, differences of about one-third of a standard deviation can be reasonably ruled out. For both groups, the mean Spielberger scores were about half a standard deviation higher (indicating greater levels of anxiety) than normative mean values — typically, 35 for adult women.[16,19] The 95% confidence interval for the mean six-item Spielberger score was 36.9 to 42.3 in the intervention group and 38.0 to 42.8 in the control group. Means for the Mental Health dimension of the SF-36, though, were not raised compared with normative values.[12]

For the 15 secondary outcomes, none were statistically significant, even before correction for multiple testing (uncorrected *P*-values ranged from 0.15 to 0.94). Confidence intervals enabled differences between the randomization groups of one-third of a standard deviation for the SF-36 scales and 0.4 standard deviations for the Impact of Events scales to be reasonably ruled out. Likewise, confidence intervals ruled out differences in the proportions with adverse (condition-specific) outcome larger than about 20% in favour of the intervention group and about 5% in favour of the control group.

At four-month follow-up, none of the comparisons between the randomization groups were statistically significant, with maximum differences in the various confidence intervals ranging from one-third to a half of a standard deviation for quantitative measures. In particular, the two mean state-anxiety scores and their 95% confidence intervals had hardly changed at this follow-up and were still markedly raised in both groups compared with normative levels.[16,19] For the categorical outcomes, confidence intervals ruled out differences larger than about 20% in favour of the intervention group, and about 10% in favour of the control group.

In terms of adherence with the follow-up smear at six months, 85% (n = 108) of the intervention group and 83% (n = 127) of the control group had attended by the close of the study (95% confidence interval for difference = -11% to +8%).

Outcomes: secondary analyses

Considerably more women in the intervention group visited their practice (73% versus 37% among controls; Table 3). Moreover, and not surprisingly given the nature of the invitation, far more women visited the practice nurse than the GP — about 3:1 in the intervention group, 1:6 among controls. Analyses that consider whether the comparison between the randomization groups was different for those who did and did not visit the practice suggested greater benefits among the former, but these interactions were mostly not statistically significant. Table 4 presents an interaction that was highly significant (P = 0.009), indicating that markedly higher state-anxiety scores were observed among women in the intervention group who did not visit the practice and women in the control group who visited the practice (most saw the GP rather than the practice nurse) on their own initiative.

On average, women in the intervention group returned the initial questionnaires two weeks later than controls (medians 49 and 37 days). However, controlling for the time interval from receipt of the smear test result and return of the initial questionnaire had no effect on the results from the primary analyses. Likewise, as anticipated, the effects of adjusting for clustering had no material effect on the results (the observed values of the intra-practice correlation coefficients for the five primary outcomes in Table 2 were, respectively, 0.024, 0.033, -0.049, 0.12, and -0.015).

Discussion

The main results from this pragmatic trial would suggest that, as an additional measure to the recognized effect of the leaflet sent to women in the trial,[8] the use of the educational intervention would result in limited benefits to women in terms of reducing levels of anxiety. This is consistent with a previous finding that,

Table 1. Basic sociodemographic characteristics for participating women according to randomization group.

	Intervention (n = 113)	Control (n = 127)
Age in years: mean (SD)	35 (11)	32 (10)
Percentage in active employment	68%	66%
Educational qualification		
A-level or above	33%	40%
GCSE/O-level/other	51%	46%
None	16%	15%

Table 2. Comparisons between intervention (n = 113) and control (n = 127) groups in terms of the five primary outcomes from the questionnaire at initial follow-up.

Outcome[a]	P-value	Proportion or meanDifference		95% CI	
		Intervention	Control		
Gynaecological health[b]	0.89	21%	22%	1.7%	(-8.7% to 12.1%)
Concern about waiting six months for repeat smear[c]	0.092	78%	88%	10.5%	(1.0% to 20.0%)
Preferred interval[d]	0.0034	53%	74%	20.9%	(9.0% to 32.9%)
Spielberger state-anxiety[e]	0.66	39.6	40.4	0.8	(-2.8 to 4.4)
SF-36 mental health[f]	0.74	73.5	72.9	-0.6	(-4.1 to 2.9)

[a]Numbers of missing data were, at most, six for these outcomes. [b]P-value from c^2 test on 3 d.f. (very/fairly poor versus average, versus fairly good, and versus very good); CI is from proportion very/fairly poor. [c]P-value from c^2 test on 2 d.f. (not at all versus a little and versus very concerned); CI is from proportion very/a little concerned. [d]P-value from c^2 test on 2 d.f. (sooner than six months versus at six months and versus no preference); CI is from proportion sooner than six months. [e]From unpaired *t*-test for six-item shortened version. [f]From unpaired t-test.

Table 3. Numbers of visits to practice staff as recorded in the initial questionnaire.

	Intervention (n = 113)		Control (n = 127)	
	Number	Percentage	Number	Percentage
Nurse	66	62	7	6
GP	23	22	39	31
Either[a]	83	73	47	37

[a]Includes 10 women who reported that they visited the practice but did not state who they saw (7 intervention and 3 control). Also, a number of women saw both the GP and the practice nurse.

Table 4. Comparison between the intervention and control groups in terms of the means of the six-item version of the Spielberger state-anxiety scale, according to whether or not the woman visited the practice.[a]

	Intervention	Control
Visited	37.8 (n = 82)	42.3 (n = 46)
Did not visit	45.4 (n = 27)	39.5 (n = 76)

[a]The sample sizes given in parentheses differ slightly from those implied by Table 3 owing to small numbers of missing values for the Spielberger score.

of two information booklets sent by post to women referred for colposcopy, the briefer version was by far the more effective in reducing anxiety.[19]

In terms of psychological distress, women in both randomization groups had higher mean Spielberger state-anxiety scores (about 40) at completion of both the six-week and the four-month questionnaires compared with available normative levels (about 35).[16,19] This is an important observation in its own right since there is a paucity of evidence about the extent to which the high levels of initial anxiety observed in the literature[8,19] are sustained during the surveillance period. On the other hand, the means for the SF-36 Mental Health dimension were similar to normative data.[12] On balance though, the data in Table 2 strongly suggest that the levels of prolonged concern among women in this trial are high. This is supported by formal analysis of the free-text comments in the present study, which at the same time indicated that, while reported levels of concern were unaffected by the intervention, knowledge of the meaning and implications of the smear test result was markedly improved.[20]

However, it remains that there was little difference between women in the intervention and control groups on standard assessments of anxiety. Of the six primary outcomes, one was significantly and markedly different between the groups in the initial questionnaire — 21% more women in the control group preferred the repeat test to be sooner than six months (74% versus 53%; 95% CI = 9% to 33%). By four months, this difference had reduced to 7% and was no longer statistically significant (95% CI = –7% to 21%). However, for none of the outcomes considered was the intervention group disadvantaged compared with the control group. Moreover, the proportion of women content to wait six months for their follow-up smear is crucial to minimizing the overall psychological morbidity associated with the screening programme and to maximizing the acceptability of the policy of surveillance.

The secondary analyses provided evidence of differences between the randomization groups according to whether or not the woman visited the practice. For women in the intervention group, the mean Spielberger state-anxiety score was higher among those who did not visit the practice, whereas in the control group it was higher among those who did. For both these sub-groups of women under surveillance for mild dyskaryosis (completing the questionnaires at home about six weeks after receiving their result), the levels of state-anxiety reached or exceeded levels observed among patients in hospital outpatient settings.[16]

While this pattern was not statistically significant for most

other outcomes, for state-anxiety, the women who appeared on average to be most anxious were those who were invited to attend for the intervention but did not visit the practice. This raises the question of whether or not these women would have been less anxious if they had not received an invitation. Alternatively, this could reflect selection effects — this group of women are potentially those who might benefit the most, but who are too anxious to attend the primary care centre. Further research into such sub-groups is clearly required, including the investigation of practical means of identifying individual preferences and needs for different amounts of risk information.

Inevitably, there are constraints on how interventions can be carried out as part of a trial. First, there is the question of bias resulting from the number of women who could not be contacted in time (in both groups) to be included in the trial. While this inevitably remains a possibility, both the low active refusal rate and the evidence available from characteristics known on participants and non-participants (in particular, age and number of partners) suggest no serious loss of generalizability. Moreover, the same procedures were applied to both randomization groups, leading to almost identical participation rates and hence groups that remained comparable. Nevertheless, in general terms, any implications for future policy must acknowledge that, in practice, the educational package may be delivered in a number of different ways. For example, in the trial, the intervention was delivered approximately four weeks after the woman received her smear test result; in practice, this is only one of several options. There are a number of opportunities for timing and selection of components of the package, including tailoring its delivery to individual women's requirements and opportunistic use of the educational package when women visit the practice rather than following an invitation.

While the differences between the groups were limited in terms of anxiety, the apparently high levels of prolonged distress observed in this trial are both consistent with and extend the evidence of psychological morbidity for women with dyskaryosis.[8,19] The personally delivered, structured educational intervention, containing a risk communication package designed to reduce anxiety, could reasonably be viewed as the best available practice. It is therefore of concern that women in the intervention group demonstrated sustained levels of anxiety over a four-month period. The research agenda thus seems to return to the fundamental question of whether surveillance should be the management of choice.

Key points

- The educational intervention had little impact on anxiety and mental health; indeed there appeared to be sustained levels of anxiety that seem relatively intractable.
- All women received a previously evaluated leaflet along with their smear test result — this may have reduced any differences between the groups in terms of anxiety at that point.
- Nevertheless, the intervention increased the proportion of women who were comfortable with a six-month interval before their next smear test.
- State-anxiety scores were particularly high among women in intervention practices who did not visit their practices, and also to some extent among control women who did; further research is needed into such sub-groups, including tailoring risk communication to individual women's requirements.
- The current policy of surveillance for mild dyskaryosis remains open to question.

References

1. Duncan I. *Guidelines for clinical practice and programme management.* NHS Cervical Screening Programme. Oxford: Hall, 1992.
2. Johnson N, Sutton J, Thornton JG, *et al*. Decision analysis for best management of mildly dyskaryotic smear. *Lancet* 1993; **342:** 91-96.
3. Flannelly G, Anderson D, Kitchener HC, *et al*. Management of women with mild and moderate cervical dyskaryosis. *BMJ* 1994; **308:** 1399-1403.
4. Wilkinson CE, Peters TJ, Stott NCH, Harvey IM. Prospective evaluation of a risk scoring system for cervical neoplasia in a primary care setting. *Br J Gen Pract* 1994; **44:** 341-344.
5. Campion MJ, Brown JR, McCance DJ, *et al*. Psychosexual trauma of an abnormal cervical smear. *Br J Obstet Gynaecol* 1988; **95:** 175-181.
6. Lerman C, Miller SM, Scarborough R, *et al*. Adverse psychologic consequences of positive cytologic cervical screening. *Am J Obstet Gynecol* 1991; **165:** 658-662.
7. Jones MH, Singer A, Jenkins D. The mildly abnormal smear: patient anxiety and choice of management. *J R Soc Med* 1996; **89:** 257-260.
8. Wilkinson C, Jones JM, McBride J. Anxiety caused by abnormal result of cervical smear test: a controlled trial. *BMJ* 1990; **300:** 440.
9. Bell JS, Kitchener HC, Fisher PM, Mann E. *Psychological response to cervical screening.* Report K/OPR/2/2/C891 to Health Services Research Committee. Edinburgh: Home and Health Department, Scottish Office, 1992.
10. Baxter K, Peters TJ, Somerset M, Wilkinson C. Anxiety among women with mild dyskaryosis: costs of an educational intervention. *Fam Pract* [in press].
11. Altman DG. *Practical statistics for medical research*. London: Chapman & Hall, 1991.
12. Jenkinson C, Coulter A, Wright L. Short form 36 (SF 36) health survey questionnaire: normative data for adults of working age. *BMJ* 1993; **306:** 1437-1440.
13. Donner A, Birkett N, Buck C. Randomization by cluster: sample size and analysis. *Am J Epidemiol* 1981; **114:** 906-914.
14. Donner A, Klar N. Methods for comparing event rates in intervention studies when the unit of allocation is a cluster. *Am J Epidemiol* 1994; **140:** 279-289.
15. Brazier JE, Harper R, Jones NMB, *et al*. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992; **305:** 160-164.
16. Spielberger CD. *State-trait anxiety inventory for adults*. Palo Alto: Consulting Psychologists Press, 1983.
17. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). *Br J Clin Psychol* 1992; **31:** 301-306.
18. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. *Psychosom Med* 1979; **41:** 209-218.
19. Marteau TM, Kidd J, Cuddeford L, Walker P. Reducing anxiety in women referred for colposcopy using an information booklet. *Br J Health Psychol* 1996; **1:** 181-189.
20. Somerset M, Baxter K, Wilkinson C, Peters TJ. Mildly dyskaryotic smear results: does it matter what women know? *Fam Pract* 1998; **15:** 537-542.

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